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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,963	08/26/2005	Peter H Seeberger	MTV-055.01	4931

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FOLEY HOAG, LLP
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EXAMINER

HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/520,963

Applicant(s)

SEEBERGER ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,9,11,12 and 19-30 is/are rejected.
- 7) ☒ Claim(s) 3,7,10 and 13-18 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>04/27/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-30 are pending in application

Claim Objections

Claims 10, 18, 30 are objected to because of the following informalities: The claims contain chemical structures, which contains representative letters of the groups attached to the rings of the said chemical structures. However, these groups are not legible. Appropriate correction is required.

Claim 30 is objected to because of the following informalities: Claim 30 does not end in with a period. However, each claim should begin with a capital letter and end with a period. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995). Appropriate correction is required.

Specification

The disclosure is objected to because of the following informalities: The specification contains figures or drawings such as the figure depicted on pages 16 and 20. However, all figures should not be incorporated within the text of disclose but should be presented on separate drawing sheets. It should be noted that a brief description of the figures should also be provided by applicant. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 19 recites the phrase "A method for preparing glycosylphatidylinositol glycans as depicted in Scheme 5". However, the claim is indefinite because compound V (the intended product) does not represent a glycosylphatidylinositol glycan. For example, when $R = R^1 = R^2 = H$; $R^7 = \text{alkyl}$; $R^3 = \text{amino}$ then compound V is not a glycosylphatidylinositol glycan (i.e., it lacks a phosphatidyl group). Consequently, the claim is indefinite and, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Furthermore, it is unclear what specific reactants are used and how they are used in said process because no method steps are recited in the claim. It should be noted that each claim must be self-contained.

Claim 27 recites the phrase "A method for preparing glycosylphatidylinositol glycans". However, the claim is indefinite because it fails to recite when or where in the process is the said glycosylphatidylinositol glycans produced. On the other hand, the claim recites the production of a tetrasaccharide.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A written description analysis involves three principle factors:

(1) field of the invention

(2) breath of the claims, and

(3) possession of the claimed invention at the time of filing for each claimed species/genus based upon the teachings of the specification and the field of the invention.

The Federal Circuit court stated that written description of an invention "requires a precise definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed Cir. 1997). The court also stated "Naming a type of material generally known to exist, in the absence as to what the material consists of is not a definition of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, adequate must describe a representative number of species of the claimed genus, and that one skilled in the art should be able to "visualize or recognize the identity of the members of the genus". *Id.*

(A) Provide a brief backdrop of the field of the invention. A reference from the BACKGROUND might very well be sufficient.

(B) Outline the scope and content of the claims briefly

(C) At the time of filing, from the disclosure, does it appear applicants were indeed in possession of the claimed invention?

Claim 19 is drawn to a method for preparing glycosylphatidylinositol glycans as depicted in a given Scheme, namely Scheme 5. The examiner notes that the knowledge and level of skill in this art would not permit one skilled in this art to assert a method or process for preparing glycosylphatidylinositol glycans and the skilled artisan could not immediately envisage the invention claimed. Applicant claims a method for preparing glycosylphatidylinositol glycans as depicted in given Scheme, namely Scheme 5. However, the disclosure is silent with regard to that which makes up and identifies the claimed method of preparing glycosylphatidylinositol

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glycans and thus lacks a clear description via art recognized procedural and methodological steps. More specifically, the applicant has not described any method steps as to how said glycosylphatidylinositol glycans are prepared. Applicant merely presents a scheme that depicts an equation but has not described any method steps as to how said glycosylphatidylinositol glycans are prepared. Furthermore, applicant has not described any specific reactants that are used nor how they are used in said method to produce the glycosylphatidylinositol glycans. Moreover, applicant has not provided an adequate representation of the mode of preparation of said glycosylphatidylinositol glycans to provide a full, clear and precise indication that applicant is in possession of the members of the methodological and procedural steps which would enable the skilled artisan to practice this invention of preparing said glycosylphatidylinositol.

Dependent claims 20-26 are also encompassed by this rejection.

Claim Rejections - 35 USC § 102

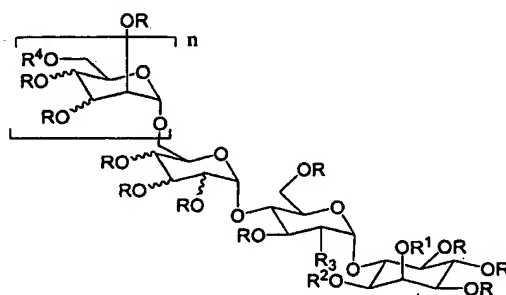
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Madsen et al. (Journal of the American Chemical Society (1995), Vol. 117. No. 5, pages 1554-1565).

In claim 1, applicant claims a compound represented by formula I:



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wherein,

n is 1-4;

R represents independently for each occurrence H, alkyl, aryl, -CH₂-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)₃;

R¹ and R² are independently H, -CH₂-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)₃; or R¹ and R² taken together are C(CH₃)₂, P(O)OH, or P(O)OR⁵;

R³ is amino, -N₃, or -NH₃X;

R⁴ represents independently for each occurrence H, alkyl, aryl, -CH₂-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)₃, or -P(O)(OR⁵)₂;

R⁵ represents independently for each occurrence H, Li⁺, Li⁺, Na⁺, K⁺, Rb⁺, Cs⁺, aryl, or an optionally substituted alkyl group; and

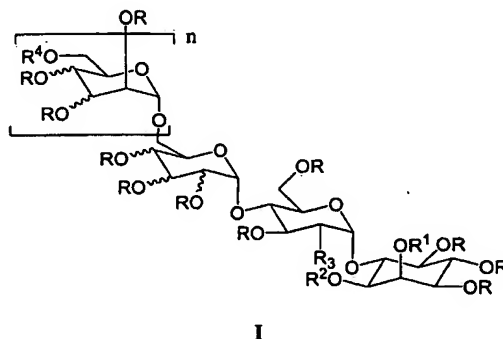
X is a halogen, alkyl carboxylate, or aryl carboxylate.

Madsen et al. disclose applicant's compound of formula I wherein n = 2; R = H; R¹ = R² = H; R³ = amino; R⁴ = H (see compound # 30, 2nd col. page 1563). Madsen et al.'s compound is called, O- α -D-mannopyranosyl-(1 \rightarrow 2)-O- α -D-mannopyranosyl-(1 \rightarrow 6)-O- α -D-mannopyranosyl-(1 \rightarrow 4)-O-2-amino-2-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6), D-myo-Inositol (see compound # 30, 2nd col. page 1563). The compound is (also called, D-myo-Inositol, O- α -D-mannopyranosyl-(1 \rightarrow 2)-O- α -D-mannopyranosyl-(1 \rightarrow 6)-O- α -D-mannopyranosyl-(1 \rightarrow 4)-O-2-amino-2-deoxy- α -D-glucopyranosyl-(1 \rightarrow 6) and it's Cas # of the compound is 123487-64-9. Claim 2 is drawn to the compound of claim 1, wherein n is 1, 2, or 3. Madsen et al. disclose applicant's compound wherein n = 2 (see compound # 30, 2nd col. page 1563). Claim 4 which is drawn to the compound of claim 1, wherein R = H is also anticipated by Madsen et al., since R = H for Madsen et al.'s compound (see compound # 30, 2nd col. page 1563). Claims 8 and 9 which are drawn to the compound of claim 1, wherein R⁴ = H ..., is also anticipated by Madsen et al., since R⁴ = H for Madsen et al.'s compound (see compound # 30, 2nd col. page 1563).

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Claims 1, 2, 6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin-Lomas et al. (Chem. Eur. J. 2000, 6, No. 19, pages 3608-3621).

In claim 1, applicant claims a compound represented by formula I:



wherein,

n is 1-4;

R represents independently for each occurrence H, alkyl, aryl, $-\text{CH}_2\text{-aryl}$, $-\text{C(O)-alkyl}$, $-\text{C(O)-aryl}$, or $-\text{Si(alkyl)}_3$;

R^1 and R^2 are independently H, $-\text{CH}_2\text{-aryl}$, $-\text{C(O)-alkyl}$, $-\text{C(O)-aryl}$, $-\text{Si(alkyl)}_3$; or R^1 and R^2 taken together are $\text{C(CH}_3)_2$, P(O)OH , or P(O)OR^5 ;

R^3 is amino, $-\text{N}_3$, or $-\text{NH}_3\text{X}$;

R^4 represents independently for each occurrence H, alkyl, aryl, $-\text{CH}_2\text{-aryl}$, $-\text{C(O)-alkyl}$, $-\text{C(O)-aryl}$, $-\text{Si(alkyl)}_3$, or $-\text{P(O)(OR}^5)_2$;

R^5 represents independently for each occurrence H, Li^+ , Li^+ , Na^+ , K^+ , Rb^+ , Cs^+ , aryl, or an optionally substituted alkyl group; and

X is a halogen, alkyl carboxylate, or aryl carboxylate.

Martin-Lomas et al. disclose applicant's compound of formula I wherein $n = 2$;

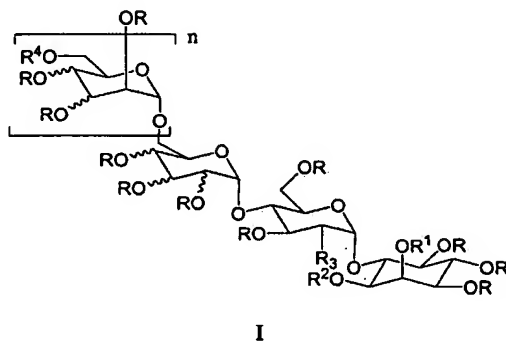
$R = -\text{CH}_2\text{-aryl} = -\text{CH}_2\text{-phenyl} = \text{Bn}$, where $\text{Bn} = \text{benzyl}$; $R^1 = R^2 = \text{H}$; $R^3 = \text{N}_3$; $R^4 = -\text{CH}_2\text{-aryl} = -\text{CH}_2\text{-phenyl} = \text{Bn}$ (see compound 3, page 3610). The Cas # of the compound is 310870-26-9.

Claim 2 is drawn to the compound of claim 1, wherein n is 1, 2, or 3. Martin-Lomas et al.

disclose applicant's compound wherein $n = 2$ (see compound 3, page 3610). Claim 6 which are

Claims 1, 2, 6, 8, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaworek et al. (Carbohydrates Research 331 (2001) 375-391).

In claim 1, applicant claims a compound represented by formula I:



wherein,

n is 1-4;

R represents independently for each occurrence H, alkyl, aryl, -CH₂-aryl, -C(O)-alkyl, -C(O)-aryl, or -Si(alkyl)₃;

R¹ and R² are independently H, -CH₂-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)₃; or R¹ and R² taken together are C(CH₃)₂, P(O)OH, or P(O)OR⁵;

R³ is amino, -N₃, or -NH₃X;

R⁴ represents independently for each occurrence H, alkyl, aryl, -CH₂-aryl, -C(O)-alkyl, -C(O)-aryl, -Si(alkyl)₃, or -P(O)(OR⁵)₂;

R⁵ represents independently for each occurrence H, Li⁺, Li⁺, Na⁺, K⁺, Rb⁺, Cs⁺, aryl, or an optionally substituted alkyl group; and

X is a halogen, alkyl carboxylate, or aryl carboxylate.

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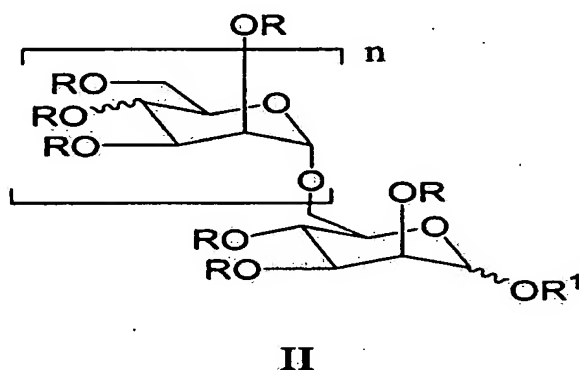
Jaworek et al. disclose applicant's compound of formula I wherein $n = 2$; $R = H$; R^1 and R^2 taken together is $P(O)OH$; $R^3 = \text{amino}$; $R^4 = H$ (see compound 5, page 376). It should be noted that although compound 5 is represented with $R^3 = NH_3^+$ and R^1 and R^2 taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein R^1 and R^2 taken together is $P(O)OH$ and $R^3 = \text{amino}$ (i.e., $-NH_2$) since at a given pH (probably in pure water) the O^- on the $P(O)O^-$ group will be protonated to give $P(O)OH$ and NH_3^+ will be deprotonated to give the amino (i.e., $-NH_2$). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form. Claim 2 is drawn to the compound of claim 1, wherein n is 1, 2, or 3. Jaworek et al. disclose applicant's compound wherein $n = 2$ (see compound 5, page 376). It should be noted that although compound 5 is represented with $R^3 = NH_3^+$ and R^1 and R^2 taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein R^1 and R^2 taken together is $P(O)OH$ and $R^3 = \text{amino}$ (i.e., $-NH_2$) since at a given pH (probably in pure water) the O^- on the $P(O)O^-$ group will be protonated to give $P(O)OH$ and NH_3^+ will be deprotonated to give the amino (i.e., $-NH_2$). That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form. Claim 5 which is drawn to the compound of claim 1, wherein R^1 and R^2 taken together is $P(O)OR^5$, is also anticipated by Jaworek et al., wherein R^5 (see compound 5, page 376). It should be noted that although compound 5 is represented with $R^3 = NH_3^+$ and R^1 and R^2 taken together = $P(O)O^-$ this compound is the same as applicant's compound wherein R^1 and R^2 taken together is $P(O)OH$ and $R^3 = \text{amino}$ (i.e., $-NH_2$) since at a given pH (probably in pure water) the O^- on the $P(O)O^-$ group will be protonated to give $P(O)OH$ and NH_3^+ will be deprotonated to give the amino (i.e., $-NH_2$).

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That is, Jaworek et al. compound is the same as applicant's claimed compound but is represented in its zwitterion form.

Claims 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rademacher et al. (WO 01/8⁵⁷45 A1).

In claim 11, applicant claims "A compound represented by formula II:



wherein,

n is 1-4;

R represents independently for each occurrence H, alkyl, aryl, $-\text{CH}_2\text{-aryl}$, $-\text{C(O)-alkyl}$, $-\text{C(O)-aryl}$, or $-\text{Si(alkyl)}_3$;

R^1 is $-(\text{CH}_2)_m\text{CH=CH}_2$ or trichloroacetimidate; and

m is 1-6.

Rademacher et al. disclose applicant's compound of formula II wherein $n = 2$;

$R = -\text{CH}_2\text{-aryl} = -\text{CH}_2\text{-phenyl} = \text{Bn}$, where Bn = benzyl and $R = -\text{C(O)-alkyl} = -\text{C(O)-t-butyl}$ (see compound 20, Scheme 5(I)). The Cas # of the compound is 371962-56-0. Claim 12 is drawn to

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the compound of claim 11, wherein n is 1, 2, or 3. Rademacher et al. disclose applicant's compound wherein n = 2 (see compound 20, Scheme 5(I)).

Allowable subject matter

Claims 3, 7, 10, 13-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Though the compounds of the present invention are similar to the compounds of the prior art, the compounds of claim 3, 7, 10, 13-18 possess structural differences to the compounds of prior art documents and these differences are not suggested in the prior art, nor are obvious over the prior art. For example, the compounds of claims 3, 7, 10, 13-18 contain different numbers of monosaccharide residues and different types of functional groups or moieties attached to their pyranose rings as compared to the compounds of the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

A handwritten signature in black ink, appearing to read 'SAJ 10/27/06', is written over a horizontal line.

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

October 24, 2006.